

Exhibit 22

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 *****

4 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
5 AND IRBESARTAN PRODUCTS

6 LIABILITY LITIGATION HON ROBERT B.
7 KUGLER

8 *****

9 THIS DOCUMENT APPLIES TO ALL
10 CASES

11 *****

12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

14

15

16 Continued Remote Videotaped via
17 Zoom Deposition of PENG DONG, commencing at
18 7:05 a.m. Hong Kong time, on the 1st of
19 April, 2021, before Maureen O'Connor Pollard,
20 Registered Diplomat Reporter, Realtime
21 Systems Administrator, Certified Shorthand
22 Reporter.

23

24 - - -

25

26 GOLKOW LITIGATION SERVICES
27 877.370.3377 ph | 917.591.5672 fax
28 deps@golkow.com

29

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<p style="text-align: right;">Page 349</p> <p>1 APPEARANCES: ALL PARTIES APPEARED REMOTELY 2 3 FOR THE PLAINTIFFS: 4 MAZIE SLATER KATZ & FREEMAN, LLC BY: ADAM SLATER, ESQ. CHERYLL A. CALDERON, ESQ. 5 CHRISTOPHER GEDDIS, ESQ. 103 Eisenhower Parkway 6 Roseland, New Jersey 07068 973-228-9898 7 aslater@mazieslater.com ccalderon@mazieslater.com 8 cgeddis@mazieslater.com 9 -and- 10 GOLDENBERG LAW, PLLC BY: MARLENE J. GOLDENBERG, ESQ. 11 800 LaSalle Avenue, Suite 2150 Minneapolis, Minnesota 55402 12 612-436-5028 mjgoldenberglaw.com 13 -and- 14 KANNER & WHITELEY, LLC BY: LAYNE HILTON, ESQ. 15 701 Camp Street New Orleans, Louisiana 70130 16 504-524-5777 17 l.hilton@kanner-law.com 18 -and- 19 HOLLIS LAW FIRM BY: IRIS SIMPSON, ESQ. 20 8101 College Boulevard, Suite 260 Overland Park, Kansas 66210 21 800-701-3672 iris@hollislawfirm.com 22 -and- 23 24</p>	<p style="text-align: right;">Page 351</p> <p>1 APPEARANCES (Continued): 2 3 FOR THE DEFENDANTS ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., PRINSTON PHARMACEUTICAL INC., HUAHAI U.S., INC., and 4 SOLCO HEALTHCARE US, LLC: 5 DUANE MORRIS, LLP BY: PATRICK C. GALLAGHER, ESQ. 6 1875 NW Corporate Boulevard Boca Raton, Florida 33431 7 561-962-2131 pcgallagher@duanemorris.com 8 -and- 9 DUANE MORRIS, LLP 10 BY: FREDERICK R. BALL, ESQ. 100 High Street 11 Boston, Massachusetts 02110 857-488-4229 12 frball@duanemorris.com 13 -and- 14 DUANE MORRIS, LLP BY: NATHAN B. REEDER, ESQ. 15 30 South 17th Street Philadelphia, Pennsylvania 19103 16 215-979-1164 nbreeder@duanemorris.com 17 18 FOR THE DEFENDANT AUROBINDO PHARMACEUTICALS: 19 CIPRIANI & WERNER, P.C. 20 BY: CAITLIN LAWLOR, ESQ. 450 Sentry Parkway 21 Blue Bell, Pennsylvania 19422 610-567-0700 22 clawlor@c-wlaw.com 23 24</p>
<p style="text-align: right;">Page 350</p> <p>1 APPEARANCES (Continued): 2 3 FOR THE PLAINTIFFS: 4 MORGAN & MORGAN BY: STEPHANIE JACKSON, ESQ. 20 North Orange Avenue, Suite 1600 5 Orlando, Florida 32801 sjackson@forthepeople.com 6 -and- 7 FLEMING NOLAN JEZ, LLP 8 BY: DAVID HOBBS, ESQ. 2800 Post Oak Boulevard 9 Houston, Texas 77056 713-621-7944 10 david_hobbs@flaming-law.com 11 12 FOR THE DEFENDANTS TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS SA, 13 INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC.: GREENBERG TRAURIG LLP 14 BY: KATE M. WITTLAKE, ESQ. 4 Embarcadero Center, Suite 3000 15 San Francisco, California 94111 415-655-1285 16 wittlakek@gtlaw.com 17 18 FOR THE DEFENDANT MYLAN PHARMACEUTICALS, INC.: 19 PIETRAGALLO GORDON ALFANO BOSICK & 20 RASPANTI, LLP BY: JOHN W. KETTERING, ESQ. 21 One Oxford Centre Pittsburgh, Pennsylvania 15219 22 412-263-1840 jk@pietragallo.com 23 24</p>	<p style="text-align: right;">Page 352</p> <p>1 APPEARANCES (Continued): 2 3 Interpreter: Dr. Yang Shao 4 Check Interpreters: Phil Hughes I Ching Ng Preston Carter 5 Videographer: Judy Diaz 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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<p>Page 354</p> <p>1 ZHP-211 Sun, et al article, Theoretical Investigation of N-Nitrosodimethylamine formation from Nitrosation of Trimethylamine..... 445</p> <p>2</p> <p>3</p> <p>4 ZHP-212 Investigation Report, Bates ZHP00662283 through 2309..... 460</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 356</p> <p>1 P R O C E E D I N G S</p> <p>2</p> <p>3 THE VIDEOGRAPHER: We are now</p> <p>4 on the record.</p> <p>5 My name is Judy Diaz. I am a</p> <p>6 legal videographer for Golkow</p> <p>7 Litigation Services.</p> <p>8 Today's date is April 1, 2021,</p> <p>9 and the time is 7:05 a.m.</p> <p>10 This remote video deposition is</p> <p>11 being held in the matter of Valsartan,</p> <p>12 Losartan, and Irbesartan Products</p> <p>13 Liability Litigation MDL.</p> <p>14 The deponent is Peng Dong.</p> <p>15 All parties to this deposition</p> <p>16 are appearing remotely and have agreed</p> <p>17 to the witness being sworn in</p> <p>18 remotely.</p> <p>19 All counsel will be noted on</p> <p>20 the stenographic record.</p> <p>21 YANG SHAO, Interpreter,</p> <p>22 having been previously duly sworn to</p> <p>23 translate the proceedings to the best of his</p> <p>24 ability, translated as follows:</p>

<p style="text-align: right;">Page 357</p> <p>1 PENG DONG, 2 having previously remotely affirmed to tell 3 the truth, was examined and testified further 4 as follows through the interpreter: 5 FURTHER EXAMINATION 6 BY MR. SLATER: 7 Q. On the screen is a portion of 8 the Drug Master File amendment filed in 9 December 2013. 10 Do you see that? 11 A. I see on the screen a document 12 in English. I cannot understand what it 13 says. I'm sorry. 14 MR. SLATER: Cheryll, can you 15 go to the first page of the document, 16 please? 17 Thank you. 18 Q. I'll start over. 19 On the screen is part of the 20 Drug Master File amendment that was filed in 21 December 2013 that we've been discussing. 22 It's dated November 10, 2013. 23 Section 3.2.S.3.2, titled "Impurities." 24 Do you see the document in</p>	<p style="text-align: right;">Page 359</p> <p>1 that section, in part it states, "Based on 2 actual residual results that DMF and MTBE 3 have never been detected in Valsartan, it is 4 demonstrated that these solvents are 5 completely removed from the manufacturing 6 process and omission of the testing is 7 justified." 8 MR. SLATER: You can translate 9 that. Would you read that -- well, 10 let me start over again. I messed up. 11 Let me start over. 12 Q. This is part of the "Residual 13 Solvents" section, and there's a heading in 14 the middle of the page that starts "DMF and 15 MTBE." 16 And it states in part in that 17 paragraph, "Based on actual residual results 18 that DMF and MTBE have never been detected in 19 Valsartan, it is demonstrated that these 20 solvents are completely removed from the 21 manufacturing process and omission of the 22 testing is justified." 23 My question is, would that 24 information have been based on the risk</p>
<p style="text-align: right;">Page 358</p> <p>1 front of you? 2 A. I do see a document in English 3 on the screen. 4 MR. SLATER: What exhibit 5 number is this, by the way, for the 6 record? Let's just get that into the 7 record. 8 MS. CALDERON: 205. 9 MR. SLATER: Thank you. 10 (Whereupon, Exhibit Number 11 ZHP-205 was marked for 12 identification.) 13 MR. BALL: I'm sorry, did you 14 say 205? 15 MR. SLATER: Yes. 16 MR. BALL: Thank you. 17 MR. SLATER: Let's go to 18 page 82. The Bates number, the last 19 four digits is 7833. 20 Scroll down, please, a little 21 bit. 22 BY MR. SLATER: 23 Q. There's a heading in the middle 24 of the page that says "DMF and MTBE." And in</p>	<p style="text-align: right;">Page 360</p> <p>1 assessment and the process validation that 2 was performed in 2011? 3 A. I wonder if the plaintiffs' 4 attorney could highlight the sentence you 5 just quoted in this paragraph, because in 6 this paragraph there's too much information, 7 and I cannot understand what it says here in 8 English. 9 Besides, can the plaintiffs' 10 attorney ask more specific questions? 11 Q. Where this says that it was 12 demonstrated that the solvents DMF and MTBE 13 were completely removed from the 14 manufacturing process, was that based on the 15 risk assessment that was performed in 2011? 16 MR. BALL: Objection. Outside 17 the scope of the 30(b)(6) topics. 18 This is a regulatory document. 19 A. I would like to ask the 20 plaintiffs' attorney whether your quotation 21 translated by the interpreter was a direct 22 quotation from the original in English from 23 this paragraph. I'm sorry, my English is not 24 good.</p>

<p>Page 361</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Can you please answer the</p> <p>3 question, sir?</p> <p>4 A. If the interpreter just</p> <p>5 translated what the plaintiffs' attorney just</p> <p>6 quoted directly from this paragraph, could</p> <p>7 you help me by further clarifying, because</p> <p>8 the scope of the question is too broad.</p> <p>9 I would like to have a more</p> <p>10 specific question, or maybe the interpreter</p> <p>11 can translate this paragraph to me, because I</p> <p>12 need to get some understanding of the</p> <p>13 context.</p> <p>14 MR. SLATER: Okay. Go off the</p> <p>15 clock.</p> <p>16 You can translate the whole</p> <p>17 paragraph for him if he wants it</p> <p>18 translated. This is off the clock.</p> <p>19 THE INTERPRETER: The</p> <p>20 interpreter is asked to translate this</p> <p>21 whole paragraph.</p> <p>22 (Interpreter translating</p> <p>23 document to witness.)</p> <p>24 A. Thank you, Interpreter. Now</p>	<p>Page 363</p> <p>1 A. This regulatory document is</p> <p>2 within the responsibility of the regulatory</p> <p>3 affairs department.</p> <p>4 I cannot determine whether this</p> <p>5 is within the topics I'm designated to</p> <p>6 testify on as a corporate witness. However,</p> <p>7 in my own capacity with regard to the</p> <p>8 question posed by the plaintiffs' attorney, I</p> <p>9 can share some of my opinions.</p> <p>10 To the best of my recollection,</p> <p>11 this regulatory document for submission is</p> <p>12 dated in 2013, according to what has been</p> <p>13 represented to me by the plaintiffs'</p> <p>14 attorney.</p> <p>15 In the risk assessment</p> <p>16 performed in 2011 with regard to DMF and MTBE</p> <p>17 during the process change, in the attachment</p> <p>18 it says DMF and MTBE needs to be further</p> <p>19 tested in the validation process.</p> <p>20 In the process validation</p> <p>21 afterwards, based on the requirements of ICH,</p> <p>22 quality standards were formulated regarding</p> <p>23 DMF and MTBE. Both solvents were tested for</p> <p>24 any residues in the process of the</p>
<p>Page 362</p> <p>1 I'm clear.</p> <p>2 MR. SLATER: Before we go on</p> <p>3 the clock, is he ready to answer the</p> <p>4 question, or is he going to keep</p> <p>5 asking me questions? Because I want</p> <p>6 to just get an answer on the record.</p> <p>7 MR. BALL: We're going back on</p> <p>8 the clock. The clock is for</p> <p>9 translation only, Adam. Please go</p> <p>10 back on the clock.</p> <p>11 MR. SLATER: Don't be so angry,</p> <p>12 Frederick. It's only the early part</p> <p>13 of the deposition. You usually don't</p> <p>14 get angry for an hour or two into it.</p> <p>15 MR. BALL: You know, what can I</p> <p>16 say. Go back on the clock.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Here's my question. Did the</p> <p>19 risk assessment performed in 2011 determine</p> <p>20 that DMF and MTBE were demonstrated to be</p> <p>21 completely removed from the manufacturing</p> <p>22 process, as stated here in this DMF?</p> <p>23 MR. BALL: Objection. Outside</p> <p>24 the scope of the 30(b)(6) topics.</p>	<p>Page 364</p> <p>1 validation.</p> <p>2 After the validation was</p> <p>3 complete, between 2012 and 2013, when</p> <p>4 valsartan was manufactured using the zinc</p> <p>5 chloride process, DMF and MTBE were</p> <p>6 continuously being tested.</p> <p>7 I believe, based on the work I</p> <p>8 just mentioned with regard to DMF and MTBE as</p> <p>9 solvents, the conclusion was strong that it</p> <p>10 has been demonstrated that DMF and MTBE could</p> <p>11 be completely removed.</p> <p>12 Q. Thank you.</p> <p>13 So the answer was yes, correct?</p> <p>14 MR. BALL: Objection.</p> <p>15 Mischaracterizes his testimony.</p> <p>16 A. I do not understand what the</p> <p>17 plaintiffs' attorney was referring to when he</p> <p>18 said "So the answer was yes."</p> <p>19 BY MR. SLATER:</p> <p>20 Q. All right. Let's go to</p> <p>21 page 147, which the last four Bates numbers</p> <p>22 are 7898.</p> <p>23 That was pretty good. We did</p> <p>24 one question in 25 minutes. We're cruising.</p>

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1 Were you told that it's
2 acceptable to take as long as you possibly
3 can and give the longest possible answer
4 possible every single time in order to take
5 up the time in our deposition? Were you told
6 that's acceptable for this deposition?
7 MR. BALL: Objection. Vague.
8 By whom?
9 BY MR. SLATER:
10 Q. You can answer.
11 MR. BALL: Before he answers --
12 you don't need to translate this.
13 Adam, he's tried to provide you
14 with a complete answer. I mean,
15 that's all I can say.
16 Okay. Go ahead.
17 MR. SLATER: Wait a second.
18 Why did you just put that in there
19 before he translates it so that -- are
20 you asking him to translate that?
21 MR. BALL: No. I'm not asking
22 him to translate what I just said.
23 MR. SLATER: I don't appreciate
24 the speaking -- I don't --

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1 MR. BALL: I said, don't
2 translate what I just said. I'm
3 telling you, if you're going to accuse
4 my witness of trying to slow down your
5 deposition, I'm going to say on the
6 record he's trying to give the best
7 answer he can to the questions you're
8 asking.
9 Now he can answer the question.
10 MR. SLATER: Please answer.
11 Please read the answer.
12 A. I would protest against such
13 statement from the plaintiffs' counsel. I
14 deem it as a personal attack on me.
15 The document presented to me by
16 the plaintiffs' attorney is in English, and
17 my English skill is poor, so I have to ask
18 the interpreter to translate the content of
19 the document to me.
20 Besides, while he was
21 translating, the time was off.
22 Q. Were you required to produce --
23 MR. SLATER: I'm sorry. What?
24 THE INTERPRETER: The witness

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1 hasn't completed the testimony yet.
2 A. I believe had the exhibits
3 presented to me been in Chinese, then we
4 would have been much more efficient.
5 With regard to the questions
6 posed by the plaintiffs' attorney, I believe
7 I have provided accurate responses in the
8 most proper way I think.
9 If the plaintiffs' attorney has
10 any questions regarding my answers, then we
11 can have a discussion. However, I believe
12 the previous question posed by the
13 plaintiffs' attorney was a personal attack on
14 me.
15 MR. SLATER: Cheryll, can you
16 scroll down so we can see the top of
17 the page also?
18 Thank you.
19 BY MR. SLATER:
20 Q. Page 147 of this document --
21 Bates 7898 are the last four digits -- is the
22 discussion about genotoxicity.
23 My question is, genotoxicity
24 was evaluated, or was supposed to be

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1 evaluated, as part of the risk assessment for
2 the zinc chloride process, correct?
3 A. I would like the plaintiffs'
4 attorney to clarify which time frame and
5 which process were you referring to.
6 Q. 2011, and I said the zinc
7 chloride process.
8 A. Okay. In 2011, during the
9 valsartan zinc chloride process change, we
10 conducted impurity analysis and risk
11 assessment based on the requirements of laws
12 and regulations, which included the risk
13 assessment on genotoxic impurities.
14 The work we conducted in 2011
15 was based on the knowledge of the
16 authorities, the industry, and ZHP.
17 Q. The 2011 risk assessment for
18 genotoxic impurities for the zinc chloride
19 process was a failure because it failed to
20 detect the presence of NDMA, correct?
21 MR. BALL: Objection.
22 Mischaracterizes his earlier
23 testimony, and calls for opinion.
24 MR. SLATER: I wasn't

<p style="text-align: right;">Page 369</p> <p>1 characterizing his testimony. I was 2 asking him a direct question. I'll 3 expect a yes or no. 4 MR. BALL: Calls for opinion 5 and expert testimony. 6 MR. SLATER: No, it doesn't. 7 It's a fact question. 8 MR. BALL: No, it isn't, Adam. 9 BY MR. SLATER: 10 Q. Go ahead and answer. 11 A. The statement provided by the 12 plaintiffs' attorney was incorrect. That was 13 not what I tried to express. 14 The risk assessment, including 15 the risk assessment of genotoxic impurities, 16 had to be performed based on the situation 17 and background at that time. 18 In 2011, the authorities, the 19 industry, and ZHP did not have any knowledge 20 of the formation of NDMA in valsartan zinc 21 chloride process. 22 Q. This has a summary and refers 23 to the EMEA CHMP guideline on the limits of 24 genotoxic impurities effective as of</p>	<p style="text-align: right;">Page 371</p> <p>1 which is the guideline that we just discussed 2 from the EMEA, and I'd like to turn now to 3 Section 4 on page 4 of 8 at the very top. 4 The first paragraph under 5 Section 4, which is titled "Toxicological 6 Background," says, "According to current 7 regulatory practice it is assumed that 8 (in vivo) genotoxic compounds have the 9 potential to damage DNA at any level of 10 exposure and that such damage may 11 lead/contribute to tumor development. Thus 12 for genotoxic carcinogens it is prudent to 13 assume that there is no discernible threshold 14 and that any level of exposure carries a 15 risk." 16 My question is, since your 17 company consulted this standard in 2011, your 18 company knew the information I just read, 19 correct? 20 A. The question posed by the 21 plaintiffs' attorney was based on the English 22 paragraph on the screen. 23 As for the content of this 24 quote in English, the interpreter already</p>
<p style="text-align: right;">Page 370</p> <p>1 January 1, 2007. 2 Was that relied on by ZHP in 3 evaluating genotoxic impurities for the zinc 4 chloride process in 2011? 5 A. Based on the information I 6 collected with regard to our work done in 7 2011 as a corporate witness, when the risk 8 assessment for the impurities was performed, 9 this guideline was used as a reference. 10 MR. SLATER: Cheryll, if you 11 could, could you pull that guideline 12 up, please? It's the one that's 13 dated -- it says London, 28 June 2006 14 in the top right. 15 Thank you. 16 BY MR. SLATER: 17 Q. On the screen is Exhibit -- I 18 think we're at 206, right? 19 (Whereupon, Exhibit Number 20 ZHP-206 was marked for 21 identification.) 22 BY MR. SLATER: 23 Q. Start over. 24 On the screen is Exhibit 206,</p>	<p style="text-align: right;">Page 372</p> <p>1 translated that to me, and I already 2 understood the meaning of the quote. 3 However, could the plaintiffs' 4 attorney repeat his pending question in 5 English again so that I can fully understand 6 the question and provide an accurate answer? 7 Q. ZHP knew the information in 8 that paragraph in 2011 when it performed its 9 risk assessment on the zinc chloride process, 10 correct? 11 A. As the corporate witness, I 12 retrospectively reviewed many documents and 13 noticed that ZHP used this official document 14 as a reference when they performed the risk 15 assessment. 16 As for the person that was 17 performing the risk assessment, whether he or 18 she specifically paid attention to what has 19 been quoted by the plaintiffs' attorney 20 regarding the background, I'm not sure. 21 Q. Let's go now to page 5 of 8. 22 The very bottom of the page is Section 5.2.3. 23 Section 5.2.3 of this document, 24 which ZHP relied on in 2011, as you've told</p>

<p style="text-align: right;">Page 373</p> <p>1 us, is titled "Application of a Threshold of 2 Toxicological Concern." 3 MR. SLATER: And what I'd like 4 to do is turn to the next page to go 5 to a paragraph in the middle of the 6 next page as part of this. 7 Perfect. 8 Q. It says right in the middle of 9 the page, "Some structural groups were 10 identified to be of such high potency that 11 intakes even below the threshold of 12 toxicological concern" -- "TTC" -- "would be 13 associated with a high probability of a 14 significant carcinogenic risk." And then it 15 cites "(Cheeseman et al. 1999 and Kroes 16 et al. 2004)." 17 "This group of high potency 18 genotoxic carcinogens comprises 19 aflatoxin-like, N-nitroso-, and 20 azoxy-compounds that have to be excluded from 21 the threshold of toxicological concern 22 approach. Risk assessment of members of such 23 groups require compound-specific toxicity 24 data."</p>	<p style="text-align: right;">Page 375</p> <p>1 Q. Can you answer my question, 2 which is, all the information we've gone 3 over -- rephrase. 4 Can you answer my question that 5 all of the information in this guideline from 6 the EMEA, the European Medicines Agency, was 7 also available and known to ZHP in conducting 8 the risk assessment for the TEA process with 9 sodium nitrite quenching, correct? 10 MR. BALL: Objection. Vague 11 with time frame. 12 But, Peng, to the degree you 13 can answer his question yes or no -- 14 MR. SLATER: 2011. 15 MR. BALL: -- please try to do 16 so. To the degree you need to expand 17 upon it to answer thoroughly, feel 18 free. 19 A. What format of knowledge are 20 you referring to when you were saying that in 21 2011, when ZHP was conducting risk assessment 22 for TEA process, the information on the 23 screen was already known to ZHP? 24 ///</p>
<p style="text-align: right;">Page 374</p> <p>1 That information was known to 2 ZHP in 2011, correct? 3 A. Based on the information I 4 collected as a corporate witness, in 2011 5 when ZHP conducted impurity risk assessment 6 for valsartan zinc chloride process change, 7 we used this document shown on the screen as 8 a reference. 9 With regard to the description 10 provided by the plaintiffs' attorney 11 specifically and translated by the 12 interpreter, ZHP conducted risk analysis or 13 risk assessment for sodium nitrite during the 14 valsartan zinc chloride process change in 15 2011. 16 Q. And all of the information we 17 went through from this guidance was known to 18 ZHP when it conducted the risk assessment for 19 the TEA process with sodium nitrite 20 quenching, correct? 21 A. For the triethylamine process, 22 based on the requirements of laws and 23 regulations, ZHP likewise conducted testing 24 of sodium nitrite.</p>	<p style="text-align: right;">Page 376</p> <p>1 BY MR. SLATER: 2 Q. Was the risk assessment for the 3 TEA process with sodium nitrite quenching 4 conducted in 2011? 5 A. I'm sorry, but could you ask 6 your question more specifically? 7 Q. No. I wouldn't know how to do 8 that. 9 A. The interpreter's translation 10 was very clear to me, but still I cannot 11 understand your question. 12 Maybe you can clarify what your 13 question is or what you were referring to so 14 that I can provide an accurate answer. 15 Q. When did ZHP conduct the risk 16 assessment for the TEA process with sodium 17 nitrite quenching to manufacture valsartan? 18 A. Based on the documents I 19 reviewed as a corporate witness, I believe it 20 was conducted in 2011. 21 MR. SLATER: Cheryll, if you 22 have the next document, the EMA 23 document, the "Questions and answers 24 on the 'Guideline on the limits of</p>

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1 genotoxic impurities," I'd like to
2 pull that up, please.
3 MS. CALDERON: I would need a
4 minute on that, so...
5 MR. SLATER: Forget it, then.
6 Let's go back -- let's take this
7 document down and let's go back to the
8 DMF, page 147, where we were before,
9 and then we're going to go from there
10 to the FDA guidance document that's
11 referenced, the FDA draft guidance.
12 BY MR. SLATER:
13 Q. Going back to the discussion
14 about genotoxicity, in the summary, after
15 referencing the EMEA guideline, it also
16 referenced FDA draft guideline "Genotoxic and
17 Carcinogenic Impurities in Drug Substances
18 and Products: Recommended Approaches," which
19 it states "is applicable to the applications
20 for existing active substances."
21 That was another guidance that
22 was relied on in 2011 by ZHP in performing
23 its risk assessments of both TEA process with
24 sodium nitrite quenching and TEA process with

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1 zinc chloride, correct?
2 A. Based on the FDA guideline
3 mentioned by the plaintiffs' counsel, which
4 is in English and is also shown on the
5 screen, and based on the document shown now
6 on the screen, I am able to draw the same
7 conclusion.
8 Q. Can you read that first
9 paragraph in English? Are you able -- I'm
10 not asking you to, but are you able to?
11 A. I can recognize certain words;
12 for example, "impurities," "FDA," "drug."
13 MR. SLATER: Cheryll, you said
14 you found the EMA question and answer
15 document, so let's put that up first.
16 Okay.
17 I've now put on the screen --
18 before we get to the FDA guideline, I
19 have the EMA "Questions and answers on
20 the 'Guideline on the limits of
21 genotoxic impurities'" up on the
22 screen, which I think is Exhibit 207
23 now.
24 ///

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1 (Whereupon, Exhibit Number
2 ZHP-207 was marked for
3 identification.)
4 BY MR. SLATER:
5 Q. What I'm going to do is -- this
6 is dated September 23, 2010.
7 MR. SLATER: I'd like to turn
8 to the second page, please, Section 2.
9 Q. And right in the middle of the
10 page, it says -- it talks about levels of
11 mutagenic impurity right in the middle of the
12 page, and what I want to focus on, where it
13 talks about the standard of "as low as
14 reasonably practical" guideline, it says
15 ALARP considerations can apply "unless it is
16 a structure of very high concern; for
17 example, N-nitroso compounds."
18 My question is this. ZHP knew
19 in 2011 that N-nitroso compounds were
20 structures of very high concern, correct?
21 A. I would like to ask the
22 plaintiffs' attorney what "ALARP" means. I
23 don't understand what it means.
24 Q. As stated in Question 2 just

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1 above what I read, it means "as low as
2 reasonably practicable."
3 It actually says, to give you a
4 little more information, Question 2 starts
5 out stating, "The guideline indicates that it
6 is necessary to reduce a known or suspected
7 mutagenic impurity to as low as reasonably
8 practicable (ALARP) even if the level is
9 below the threshold of toxicological concern
10 (TTC)."
11 I hope that helps.
12 A. Okay. Thank you very much.
13 Could you repeat your question again?
14 Q. As stated on this page,
15 N-nitroso compounds are described as "a
16 structure of very high concern" as part of
17 Section -- Question 2, the answer.
18 That was known to ZHP in 2011,
19 correct?
20 A. In 2011, based on the knowledge
21 of the authorities, the industry, and ZHP, we
22 conducted our corresponding work. For
23 example, for sodium nitrite, we added testing
24 of residual sodium nitrite in the validation

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1 batches.

2 MR. BALL: Peng, to the degree

3 you can answer the question he asked

4 in a yes or no, or if you have to

5 qualify it, that's fine.

6 And, Adam -- please don't

7 translate the rest of this,

8 Dr. Shao -- Adam, we've gone about

9 75 minutes plus with translation, so

10 maybe we can try to get this question

11 answered and take a break.

12 MR. SLATER: Okay.

13 A. Okay. Thank you.

14 BY MR. SLATER:

15 Q. Did -- rephrase.

16 Was ZHP aware in 2011 that

17 N-nitroso compounds were structures to be of

18 very high concern according to the European

19 Medicines Agency? Yes or no.

20 A. Your question is not a simple

21 answer that I can simply answer with a yes or

22 no.

23 In 2011, ZHP conducted

24 corresponding work based on the knowledge of

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1 the authorities, the industry, and ZHP

2 valsartan zinc chloride process at that time.

3 The authorities also included EDQM.

4 MR. SLATER: Go off the record.

5 THE VIDEOGRAPHER: The time

6 right now is 8:25 a.m. We're now off

7 the record.

8 (Whereupon, a recess was

9 taken.)

10 THE VIDEOGRAPHER: The time

11 right now is 8:42 a.m. We're back on

12 the record.

13 BY MR. SLATER:

14 Q. At the very bottom of page 2,

15 this refers to "a class of very potent

16 genotoxic carcinogens," and that includes,

17 according to this, N-nitroso compounds.

18 You agree that a N-nitroso

19 compound is a very potent genotoxic

20 carcinogen, correct?

21 MR. BALL: Objection. Calls

22 for opinion.

23 A. I need the plaintiffs' attorney

24 to point out where that statement is on this

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1 page; and, if possible, I would like

2 interpreter to translate the context.

3 MR. SLATER: Great. Go off the

4 time.

5 It's the very bottom, number 3,

6 little three iii's. It says, "Yes,

7 genotoxicity testing."

8 You can translate that for him

9 if you'd like.

10 (Interpreter translating

11 document to witness.)

12 A. Now I'm clear. Thank you,

13 Interpreter.

14 MR. BALL: Back on the timer,

15 please.

16 MR. SLATER: Is he answering or

17 is he talking?

18 Okay. Let's go back on the

19 timer.

20 We're all talking over each

21 other. Let's stop for one second.

22 Sorry, Dr. Shao.

23 BY MR. SLATER:

24 Q. We're back on the timer.

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1 Please answer the question.

2 A. I would like the question to be

3 repeated because it took some time for the

4 translation. I'm sorry.

5 Q. This says that N-nitroso

6 compounds belong to a class of very potent

7 genotoxic carcinogens.

8 You agree with that, correct?

9 MR. BALL: Objection. Calls

10 for opinion and expert testimony.

11 A. From the plaintiffs' attorney's

12 statement as well as the interpreter's

13 interpretation for the corresponding content,

14 now I understand what it says on the screen

15 in English, which matches the statement of

16 the plaintiffs' attorney.

17 However, I'm not a

18 toxicologist. I'm not able to provide a

19 corresponding accurate judgment.

20 BY MR. SLATER:

21 Q. What I just read was known to

22 ZHP in 2011, correct?

23 A. Are you referring to the third

24 paragraph on the screen translated by the

<p style="text-align: right;">Page 385</p> <p>1 interpreter just now by saying what I just 2 read? 3 Q. Yes. 4 A. As a corporate witness, based 5 on the information I collected, after 6 reviewing certain documents, ZHP did use this 7 regulatory document as a reference during 8 valsartan's zinc chloride process change in 9 2011. 10 However, in my personal opinion 11 as to whether the specific operator paid 12 attention to the third paragraph on the 13 screen that was just quoted by the 14 plaintiffs' attorney, I cannot give an 15 affirmative answer. In other words, I'm not 16 sure. 17 However, during the valsartan 18 zinc chloride process validation in 2011, ZHP 19 did add testing for sodium nitrite. 20 MR. SLATER: Let's take this 21 document down, and let's put up the 22 Guidance for Industry from the FDA. 23 This is Exhibit 208. It's the 24 FDA Guidance for Industry regarding</p>	<p style="text-align: right;">Page 387</p> <p>1 effort should be made to prevent the 2 formation of genotoxic or carcinogenic 3 compounds during drug substance synthesis or 4 drug product manufacturing." 5 A. I'm -- I was paying a lot of 6 attention to the interpreter's translation. 7 Can you please repeat your question? 8 Q. Do you agree with the statement 9 that I just read to you from this FDA 10 guidance document? 11 A. As for this guidance document, 12 in my personal opinion, since it is a legal 13 document, I'm not able to evaluate it with a 14 simple yes or no. 15 Q. Are you refusing to answer the 16 question? 17 MR. BALL: Hold on. That's not 18 what he said. He said he can't answer 19 your question. Maybe if you rephrased 20 it. 21 MR. SLATER: Really? Like four 22 or five times for the next half-hour, 23 maybe? 24 MR. BALL: Adam, if that's what</p>
<p style="text-align: right;">Page 386</p> <p>1 Genotoxic and Carcinogenic Impurities 2 in Drug Substances and Products: 3 Recommended Approaches that was cited 4 in the DMF update in December 2013. 5 (Whereupon, Exhibit Number 6 ZHP-208 was marked for 7 identification.) 8 MR. SLATER: What I would like 9 to do now is turn to page 7, please. 10 BY MR. SLATER: 11 Q. Section IV is titled 12 "Recommended Approaches" -- let me rephrase 13 that. 14 Looking now at Section IV-A, 15 titled "Prevention of Genotoxic and 16 Carcinogenic Impurity Formation," I'm going 17 to read something, Mr. Dong, and I'm going to 18 ask you to listen to this and tell me if ZHP 19 agrees with this statement, okay? 20 And I'm going to now read it. 21 "Since drug-related impurities presumably 22 provide limited, if any, therapeutic benefits 23 and because of their potential to cause 24 cancer in humans, every feasible technical</p>	<p style="text-align: right;">Page 388</p> <p>1 it takes, feel free. I can't help how 2 you're asking questions. 3 MR. SLATER: I don't know why 4 you're -- I don't need to be 5 addressed. I'm looking at the 6 document. I don't need to be coached. 7 Thank you. 8 BY MR. SLATER: 9 Q. You realize -- well, rephrase. 10 Does ZHP agree with the 11 statement that I read, quoting from the FDA 12 guidance document? 13 A. I think as for this FDA 14 guidance document, we as a company cannot say 15 we agree or don't agree. Rather, we should 16 conduct our work based on our current 17 knowledge as well as the requirement of this 18 guidance document. 19 Q. One feasible technical effort 20 to prevent -- rephrase. 21 It would have been feasible to 22 perform gas chromatography-mass spectrometry 23 to see if there were any nitrosamine 24 impurities as part of the risk assessment.</p>

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1 That would have been feasible,
 2 correct?
 3 MR. BALL: Objection.
 4 Speculative.
 5 A. In 2011, during the development
 6 of valsartan zinc chloride process, ZHP
 7 conducted our work based on the knowledge
 8 then.
 9 However, at that time, the
 10 authorities, the industry, or ZHP did not
 11 have any knowledge on the nitrosamine
 12 impurities, including its detection methods.
 13 BY MR. SLATER:
 14 Q. We'll come back to that.
 15 ZHP did use mass spectrometry
 16 to evaluate potential impurities as part of
 17 its risk assessment for the zinc chloride
 18 process, correct?
 19 A. I'm sorry, but I do not
 20 understand your question. I wonder if you
 21 can break this question into shorter ones
 22 since it's a little bit too long to me, and
 23 then ask shorter questions one by one, or you
 24 can ask a more specific question.

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1 Q. No, I don't think we're going
 2 to do that. We're not going to bleed the
 3 clock much longer on this one.
 4 MR. SLATER: Go to page 8, the
 5 top of page 8, please, Cheryll.
 6 Q. ZHP was aware from this
 7 document that N-nitroso structures "have
 8 extremely high carcinogenic potency and are
 9 excluded from the threshold approach," as it
 10 states at the bottom of the top carryover
 11 paragraph. ZHP knew that in 2011, correct?
 12 A. The interpreter already
 13 provided me with a very clear translation;
 14 however, I do not get your question because
 15 it's a little bit too long. Can you break
 16 into shorter ones or ask more specific
 17 questions?
 18 Q. From -- rephrase.
 19 Based on this document -- well,
 20 rephrase.
 21 As stated in this document,
 22 N-nitroso compounds "have extremely high
 23 carcinogenic potency and are excluded from
 24 the threshold approach."

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1 ZHP knew that in 2011, correct?
 2 A. I'm not quite sure what you
 3 mean by "excluded from the threshold
 4 approach."
 5 Q. ZHP knew in 2011 that N-nitroso
 6 compounds such as NDEA and NDMA had extremely
 7 high carcinogenic potency, knew that in 2011,
 8 correct?
 9 MR. BALL: Objection. Calls
 10 for expert testimony.
 11 BY MR. SLATER:
 12 Q. Answer the question, please.
 13 A. I would like to tell you that I
 14 don't quite get your question. What form of
 15 knowledge are you referring to by ZHP knew in
 16 2011?
 17 Q. You're asking me to define what
 18 it means to know something?
 19 A. I would like you to be more
 20 specific; for example, the form of the
 21 knowledge or the scope of the knowledge.
 22 Q. This document was known to ZHP
 23 in 2011, and ZHP knew all the contents,
 24 including that sentence I read, correct?

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1 A. I'm sorry. I need you to point
 2 out where the sentence you just referred to
 3 is in this paragraph, and then I would like
 4 to ask the interpreter to translate for me.
 5 MR. SLATER: Go off the timer.
 6 Dr. Shao, it's at the top, the
 7 carryover paragraph. There's a
 8 sentence that starts, "However, there
 9 are some compounds."
 10 Do you see that?
 11 THE INTERPRETER: Yes.
 12 MR. SLATER: It's that sentence
 13 that I'm reading.
 14 (Interpreter translating
 15 document to witness.)
 16 THE INTERPRETER: The
 17 interpreter is asked to translate the
 18 whole paragraph.
 19 MR. SLATER: Hey, I'm not the
 20 guy trying to get out of Macao on
 21 Thursday night or Friday morning, so
 22 if he wants you to translate -- you're
 23 talking about starting on the prior
 24 page? Go ahead. Have at it. You can

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1 go back. As long as he wants to
 2 spend -- I don't know what else to
 3 tell him. I mean, it's a really long
 4 paragraph.
 5 (Interpreter translating
 6 document to witness.)
 7 A. I believe I need to understand
 8 the background or the context of this
 9 sentence in order to give you a response
 10 that's accurate.
 11 BY MR. SLATER:
 12 Q. You don't have to explain
 13 yourself to me if you want Dr. Shao to read
 14 it to you. But we're not on the clock, and
 15 we're not going to go until 3:00 o'clock in
 16 the morning tonight. So all I'm saying is
 17 we're probably going to be continuing Friday
 18 night. That's all I'm saying.
 19 MR. BALL: Adam, you don't get
 20 to make that decision.
 21 MR. SLATER: So we're just
 22 going to go until 3:00 in the morning
 23 tonight?
 24 MR. BALL: No. We're going to

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1 go the five hours of translation time
 2 that you are allowed.
 3 MR. SLATER: Okay. Well, thank
 4 you for telling me what I'm going to
 5 do, but, you know, this --
 6 MR. BALL: No, I'm not telling
 7 you what you're going to do.
 8 MR. SLATER: We're going to do
 9 this for 15, 20 minutes now, this
 10 paragraph, on a simple question.
 11 Maybe there's an easier way
 12 through this if you suggest -- well,
 13 you do whatever you want. I'm not
 14 going to --
 15 MR. BALL: You already said I
 16 shouldn't coach you on how to ask
 17 questions, Adam.
 18 MR. SLATER: I'm sorry. I
 19 don't know how to ask questions?
 20 MR. BALL: I said you already
 21 suggested I should not help you ask
 22 questions.
 23 MR. SLATER: No, you shouldn't.
 24 MR. BALL: So...

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1 MR. SLATER: I was going to
 2 say, possibly suggest to your client
 3 there's an easier way to do this.
 4 How about this. I'll do you a
 5 favor here. Let's go back on the
 6 timer.
 7 BY MR. SLATER:
 8 Q. Does ZHP agree or disagree with
 9 the FDA's statement that N-nitroso compounds
 10 have extremely high carcinogenic potency?
 11 MR. BALL: Objection. Calls
 12 for expert testimony.
 13 A. May I proceed to answer?
 14 MR. BALL: Please.
 15 BY MR. SLATER:
 16 Q. That would be wonderful.
 17 A. As a company, I don't think we
 18 can simply agree or disagree with FDA's
 19 corresponding guidelines. What we were
 20 supposed to do was to conduct the
 21 corresponding work based on the requirements
 22 of the laws and regulations at that time.
 23 Q. That includes conducting the
 24 work in accordance with this guidance

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1 document, correct?
 2 A. From the document you just
 3 showed me on the screen, which was a document
 4 that ZHP submitted to FDA, I saw that
 5 corresponding work was conducted using this
 6 FDA's guidance document as a reference.
 7 MR. SLATER: Cheryll, let's go
 8 to the last page of this document,
 9 page 13, the Decision Tree Flow
 10 Diagram.
 11 Q. Appendix A to this FDA guidance
 12 is a Decision Tree Flow Diagram, and the
 13 first thing in the flow is to identify the
 14 impurity.
 15 Do you see that at the top of
 16 the flowchart?
 17 A. Are you referring to the box on
 18 top of this flowchart which has an English
 19 word followed by the word "impurity"?
 20 Q. Yes, I am.
 21 A. I do see that box.
 22 Q. And you agree that in trying to
 23 prevent genotoxic impurities, the most
 24 important thing to do is to identify that the

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1 impurities are there, correct?

2 A. I disagree with your statement.

3 The work conducted involved many departments,

4 and it was very complex and complicated.

5 Therefore, it is not appropriate to say

6 certain work was very important or the most

7 important.

8 Q. If you don't identify the

9 impurity -- withdrawn. It doesn't matter.

10 It's obvious.

11 MR. SLATER: Let's go back to

12 the DMF, page 148 of the DMF, please,

13 Cheryl.

14 Scroll up a little more.

15 Perfect.

16 Q. Looking now at page 148 of the

17 DMF dated November 10, 2013, this is the

18 Discussion on Impurities and the table of

19 organic impurities.

20 MR. SLATER: What I'd like to

21 do is scroll down, please, to the text

22 at the bottom of the page.

23 Q. And this says in part, "there

24 is not any high potency genotoxic group, such

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1 as, aflatoxin-like, N-nitroso-, and

2 azoxy-compound has been included in these

3 impurities." I'm going to stop there.

4 That was part of the risk

5 assessment performed in 2011, that statement,

6 correct?

7 A. I need you to point out which

8 paragraph and which sentence you just quoted.

9 I would like the interpreter to translate the

10 whole paragraph in order to understand the

11 context.

12 MR. SLATER: Go off the timer.

13 It's the last paragraph on the

14 page that starts, "Regarding of the

15 impurity D-J."

16 A. Okay. Thank you, Interpreter.

17 I'm ready to answer a question.

18 Q. Okay. Go ahead and answer the

19 question, please.

20 A. I'm sorry. It took some time

21 for the interpreter to translate the

22 document, so would you please repeat the

23 pending question?

24 Q. The statement that "there is

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1 not any high potency genotoxic group, such

2 as, aflatoxin-like, N-nitroso-, and

3 azoxy-compound has been included in these

4 impurities."

5 That was a statement based on

6 the risk assessment performed in 2011,

7 correct?

8 A. That's not correct.

9 MR. BALL: Adam, I just want to

10 make sure we went back on the timer.

11 A. With regard to your question

12 quoting the sentence in English in the last

13 paragraph on the screen, as well as the

14 information I collected through the

15 translation of the two paragraphs by the

16 interpreter, I believe ZHP had this statement

17 based on the impurities D and J, or "D to J

18 and hydrolysis product," which is the prior

19 sentence to the sentence you just quoted.

20 BY MR. SLATER:

21 Q. The basis of that statement was

22 the risk assessment that was conducted by

23 ZHP, correct?

24 A. I would like you to clarify

Page 400

1 what you are referring to by that statement.

2 MR. SLATER: Scroll up to the

3 top of the table.

4 Perfect.

5 Q. At the top of the page where it

6 says "Organic impurities," ZHP wrote in this

7 document "All the potential organic

8 impurities are demonstrated in Valsartan

9 listed as follows," and then there's that

10 whole table.

11 And nowhere does it include

12 NDMA, correct?

13 A. Where it says "all the

14 potential organic impurities" was based on

15 the knowledge and understanding at that time.

16 That's the validation and the conclusion we

17 made.

18 Q. That was also based on the

19 failure of the scientific analysis to be

20 thorough in performing the risk assessment,

21 correct?

22 MR. BALL: Objection. Calls

23 for opinion.

24 A. What you said is not correct.

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1 In 2011, when ZHP was
 2 conducting valsartan zinc chloride process
 3 change, our work was based on the knowledge
 4 of the authorities, the industry, and ZHP at
 5 the time.
 6 The scientific method for the
 7 potential impurity analysis was also based on
 8 the understanding and knowledge at that time.
 9 BY MR. SLATER:
 10 Q. Bottom line -- withdrawn.
 11 MR. SLATER: Let's take this
 12 document down.
 13 This is a colorful one.
 14 By the way, are we at a break
 15 or should we keep going? Because I'm
 16 starting a new document.
 17 MR. BALL: We have roughly
 18 27 minutes until we've got 70 minutes.
 19 MR. SLATER: Oh, really? Okay.
 20 MR. BALL: Yes.
 21 MR. SLATER: Great.
 22 This is Exhibit 208, right?
 23 Wild guess?
 24 THE STENOGRAPHER: 209.

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1 MR. SLATER: Like I said, this
 2 is Exhibit 209.
 3 (Whereupon, Exhibit Number
 4 ZHP-209 was marked for
 5 identification.)
 6 BY MR. SLATER:
 7 Q. This is Exhibit 209, which is
 8 from the International Agency for Research on
 9 Cancer, known as IARC, and it's the "IARC
 10 Monographs on the Evaluation of the
 11 Carcinogenic Risk of Chemicals to Humans,
 12 Some N-Nitroso Compounds," and it's dated in
 13 the bottom left as May 1978.
 14 MR. SLATER: If you could just
 15 scroll up a little, Cheryll, please.
 16 Q. IARC monographs --
 17 MR. BALL: Adam, I can't see
 18 the bottom.
 19 There we go. Thank you.
 20 BY MR. SLATER:
 21 Q. IARC monographs were known in
 22 the scientific community well before and
 23 certainly as of 2011, correct?
 24 MR. BALL: Objection. Calls

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1 for speculation and vague.
 2 MR. SLATER: All right. I'll
 3 ask it differently then.
 4 Well, actually, no, I won't.
 5 I'll ask it differently but ask the
 6 same question.
 7 BY MR. SLATER:
 8 Q. IARC monographs were well-known
 9 in the scientific community by 2011, correct?
 10 MR. BALL: Objection. Calls
 11 for speculation.
 12 A. I am not able to provide an
 13 accurate answer.
 14 As for the validation in the
 15 scientific community, I believe it is beyond
 16 the scope of the topics I am designated to
 17 testify on.
 18 BY MR. SLATER:
 19 Q. ZHP knew of the existence of
 20 IARC monographs by 2011, correct?
 21 A. I cannot provide you with an
 22 accurate answer. By 2011, ZHP might have
 23 known or might have not known the existence.
 24 I haven't reviewed any related documents, so

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1 I cannot give you an accurate answer.
 2 Q. What documents did you review
 3 to prepare for this deposition?
 4 MR. BALL: Objection to the
 5 degree that it goes to --
 6 MR. SLATER: I didn't ask the
 7 question in a way that would invade on
 8 privilege.
 9 BY MR. SLATER:
 10 Q. Answer the question.
 11 MR. BALL: Adam, can I finish,
 12 please? I get to make my -- you get
 13 to ask your questions; I get to make
 14 my objections.
 15 Objection on the basis of the
 16 attorney/client privilege. To the
 17 degree they're documents that he
 18 reviewed with counsel, please don't
 19 disclose those.
 20 MR. SLATER: That's an
 21 inappropriate objection. I did not
 22 ask him that. You're feeding
 23 something into it to try to convolute
 24 the question.

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1 MR. BALL: We're not. You
2 asked him what documents did he
3 review.
4 MR. SLATER: That's all I asked
5 him.
6 MR. BALL: Yes, and I'm telling
7 him he can answer to the extent they
8 weren't documents that we showed him.
9 MR. SLATER: That's an improper
10 instruction.
11 MR. BALL: I disagree.
12 BY MR. SLATER:
13 Q. What documents did you review
14 to prepare for this deposition?
15 MR. BALL: Same objection.
16 A. As a corporate witness for this
17 deposition, I reviewed documents related to
18 our previous work; for example, the process
19 change document that we have been discussing
20 about over the past few days, validation
21 documents, as well as batch records.
22 BY MR. SLATER:
23 Q. Is that all you reviewed?
24 A. Since you're asking for all the

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1 documents, would ICH document be counted?
2 Q. Yes.
3 A. I did review some ICH
4 documents. As for the others, it happened
5 some time ago, and I do not recall.
6 Q. Are those documents that you
7 reviewed in a file, either in paper or on
8 computer?
9 A. Some of the documents I
10 reviewed, such as process procedures,
11 changes, validations, batch records, are in
12 the hard-copy form stored in an archive.
13 Q. Did you review any IARC
14 monographs?
15 A. I'm sorry, my English is poor.
16 What do you mean by "IARC" or the English
17 word to that effect?
18 Q. IARC, International Agency for
19 Research on Cancer.
20 A. Personally speaking, I haven't
21 reviewed this document.
22 MR. BALL: Adam, we've probably
23 gone long enough that the translator
24 needs a break.

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1 MR. SLATER: Okay.
2 THE VIDEOGRAPHER: Are we going
3 off the record?
4 MR. SLATER: Yes.
5 THE VIDEOGRAPHER: The time
6 right now is 9:49 a.m. We're now off
7 the record.
8 (Whereupon, a recess was
9 taken.)
10 THE VIDEOGRAPHER: The time
11 right now is 10:06 a.m. We're back on
12 the record.
13 MR. SLATER: That is not the
14 document, Cheryll.
15 Cheryll, please take that down.
16 Cheryll.
17 MR. BALL: Adam, I didn't look
18 at it at all, I swear.
19 MR. SLATER: It's our chat, but
20 I hope it wasn't -- if it's recorded,
21 I'm going to ask to have it edited out
22 if possible. Do you mind?
23 MR. BALL: No, I don't mind. I
24 know that was a technological error.

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1 I'm not going to -- in the same way I
2 don't think you want to see the texts
3 that I'm sending to Patrick during the
4 deposition.
5 MR. SLATER: Unless you're
6 telling him what's going on in the
7 last four minutes of the Knicks game,
8 which I'm now missing when it's a
9 two-point game, then no.
10 MR. BALL: I am not. Although
11 I am going to point out that it's the
12 women's final, NCA final, on next
13 Sunday for Mr. Gu -- for Dr. Gu, so I
14 find that highly disappointing.
15 MR. SLATER: All right. Let's
16 go on the clock.
17 And, Cheryll, let's go to
18 page 36, please.
19 That's not the right page.
20 That's page 38.
21 MS. CALDERON: You cut out.
22 Can you repeat the page?
23 MR. SLATER: Page 36.
24 Probably talking too soft as

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1 usual.
2 BY MR. SLATER:
3 Q. Looking at the third paragraph,
4 the first sentence says, "It has been known
5 since 1865 that the reaction of dimethylamine
6 hydrochloride with sodium nitrite at an
7 acidic pH yields N-nitrosodimethylamine,"
8 which I think we can agree is NDMA.
9 Did ZHP have that knowledge in
10 2011?
11 THE INTERPRETER: The
12 interpreter is asked to repeat the
13 rendition.
14 MR. SLATER: One second. Is he
15 asking you to translate it for him?
16 THE INTERPRETER: No.
17 MR. SLATER: All right. Go
18 ahead, read it again.
19 THE INTERPRETER: Signal is not
20 stable, so the witness --
21 MR. SLATER: Okay, it's fine.
22 It's fine. You don't have to explain,
23 Dr. Shao. You can just read it to
24 him.

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1 A. In 2011, ZHP had no knowledge
2 of the formation of NDMA during the valsartan
3 zinc chloride process.
4 Considering the English
5 sentence you just quoted, by now ZHP has
6 never manufactured valsartan using
7 dimethylamine hydrochloride in the process.
8 Q. The zinc chloride process was
9 yielding dimethylamine, which was then
10 reacting with nitrous acid to create NDMA,
11 correct?
12 A. I would like you to clarify
13 which time frame or what context you're
14 referring to in your question.
15 Q. The entire time ZHP
16 manufactured valsartan with the zinc chloride
17 process, the process was yielding
18 dimethylamine, which was reacting with
19 nitrous acid to form NDMA, correct?
20 A. During the development of
21 valsartan zinc chloride process in 2011, ZHP
22 had no knowledge of the formation of NDMA in
23 the valsartan zinc chloride process.
24 Q. Can you answer my question,

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1 please, as to what you know right now,
2 speaking for ZHP?
3 MR. SLATER: Actually, I'm not
4 going to ask. I asked it twice; he
5 doesn't want to answer it. We'll seek
6 our remedy.
7 Once --
8 MR. BALL: Hold on. I'm sorry,
9 I was muted.
10 I disagree with the proposition
11 that he doesn't want to answer it. He
12 tried to answer it.
13 Maybe if you rephrase the
14 question, Adam.
15 MR. SLATER: It's not working.
16 Every time I rephrase, I get another
17 question back. So it's just -- it's
18 like -- it's fruitless. So I'll go to
19 the next question.
20 BY MR. SLATER:
21 Q. Once ZHP learned that there was
22 dimethylamine reacting with nitrous acid in
23 the zinc chloride process, ZHP knew that it
24 had to optimize that process to prevent NDMA

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1 from forming, correct?
2 A. In 2011, ZHP had no knowledge
3 of the formation of NDMA in valsartan zinc
4 chloride process.
5 MR. BALL: I think there's
6 confusion there. I think he's asking
7 when they found out, what -- did they
8 take steps to optimize the process.
9 Is that a fair
10 characterization, Adam, of what you
11 were asking?
12 MR. SLATER: Yes.
13 A. If my attorney correctly
14 characterized your question, then my answer
15 would be as follows.
16 After June 2018, when ZHP found
17 the NDMA impurity in the valsartan zinc
18 chloride process, ZHP organized corresponding
19 departments and conducted corresponding work,
20 including optimizing the process.
21 BY MR. SLATER:
22 Q. ZHP realized that it would
23 never be appropriate to put dimethylamine
24 with nitrous acid where those two substances

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1 could react together, because there would be
2 a risk of creating NDMA, right?
3 A. Can you break this long
4 question into shorter ones and ask them one
5 by one --
6 Q. Sure.
7 A. -- or be specific in your
8 question? Because your question is a little
9 bit too long. I'm sorry.
10 Q. No problem.
11 I'm asking about the time
12 period of 2011.
13 MR. SLATER: Please tell him
14 that.
15 Q. First I want to ask about
16 dimethylamine.
17 MR. SLATER: Please tell him.
18 Q. In 2011, ZHP knew that
19 dimethylamine could react with nitrous acid
20 to form NDMA. As a matter of chemistry, ZHP
21 knew that, correct?
22 A. I would like to ask you the
23 scope and the person you're referring to by
24 "as a matter of chemistry."

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1 Q. The people in charge of the
2 risk assessments for the valsartan
3 manufacturing processes.
4 A. The key person in charge of the
5 risk assessment for valsartan zinc chloride
6 process in 2011 already left the company, so
7 I cannot offer my evaluation of his personal
8 knowledge of chemistry as a corporate
9 witness.
10 All I can do is to use the
11 documents that are available to me, such as
12 the process change, process validation, and
13 review them to find out about the
14 circumstances at that time.
15 Q. Who is that person who left the
16 company?
17 A. For example, the manager in the
18 technical department, Kai Yang, spelled as
19 K-A-I, last name Y-A-N-G.
20 Q. Did you review his notes and
21 his files?
22 A. I did review some of the
23 documents he approved.
24 Q. I guess we'll check our files

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1 to see if we have those documents. Doesn't
2 sound familiar.
3 Were those notes? Rephrase.
4 What type of documents were
5 they? Were they notes? Were they memos?
6 Were they books? What were they?
7 A. The documents I reviewed are
8 mostly the files retained by the company; for
9 example, the process change documents where
10 Kai Yang put his signature on.
11 Q. Would ZHP have ever knowingly
12 put dimethylamine and nitrous acid together
13 as part of the manufacturing process for
14 valsartan?
15 MR. BALL: Objection. Calls
16 for speculation.
17 A. In 2011, during the valsartan
18 zinc chloride process change, ZHP had no
19 specific knowledge of the formation of NDMA
20 in the valsartan zinc chloride process.
21 MR. SLATER: Cheryll, turn to
22 page 40, please.
23 Q. This paragraph says in part
24 that "The principal techniques employed by

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1 the analysis of volatile N-nitrosamines have
2 been described in a recent publication," it
3 gives the citation to Preussmann 1978, and
4 then refers to "The relative merits of high-
5 and low-resolution mass spectrometry...since
6 use of mass spectrometry as a confirmatory
7 technique is particularly important."
8 You would agree with me,
9 knowing what you know now, that mass
10 spectrometry is the best way to identify NDEA
11 and NDMA in valsartan, correct?
12 MR. BALL: Objection. Calls
13 for speculation, expert opinion, and
14 opinion.
15 MR. SLATER: Actually, I'm
16 going to withdraw the question. I'm
17 withdrawing the question. I'm asking
18 it differently.
19 BY MR. SLATER:
20 Q. This paragraph refers to the
21 use of high- and low-resolution mass
22 spectrometry to identify volatile
23 N-nitrosamines.
24 You agree that is the proper

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1 method to identify NDEA and NDMA in
2 valsartan, correct?
3 MR. BALL: Objection. Calls
4 for speculation, calls for expert
5 opinion.
6 MR. SLATER: It calls for the
7 analytical process they employed.
8 MR. BALL: No. That's not what
9 you asked, Adam. You did not ask what
10 did they employ. You asked if it's
11 the best way to do it.
12 MR. SLATER: Your objection is
13 not --
14 MR. BALL: You --
15 (Cross-talking.)
16 MR. SLATER: Why are you
17 yelling over me?
18 MR. BALL: I'm not trying to
19 yell over you. I'm trying to finish
20 my -- you interrupted me, and you
21 said, that's what I said, and that's
22 not what you said.
23 MR. SLATER: You just said that
24 my question is speculative when you

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1 know that's exactly what they did.
2 MR. BALL: No, Adam, I didn't.
3 Your question was "Is it the best
4 way." Then you said, "What I asked is
5 what did they use."
6 That's a totally different
7 question. If you want to ask what did
8 they use, that's not speculative.
9 MR. SLATER: All right. Are we
10 going to now -- I don't want this
11 interpreted for the witness.
12 MR. BALL: It doesn't need to
13 be interpreted. I'm not asking --
14 MR. SLATER: Then let's have
15 him answer.
16 MR. BALL: I do want my
17 objection interpreted, though.
18 MR. SLATER: Why?
19 MR. BALL: Because it's
20 speculative the way you formed the
21 question.
22 MR. SLATER: Why does he need
23 to know what you're saying? So he can
24 then --

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1 (Cross-talking.)
2 MR. BALL: No. I said it is
3 speculative and calls for expert
4 opinion is a totally proper objection,
5 given how you phrased the question.
6 MR. SLATER: I don't understand
7 why you want your client to hear that
8 you said that. He always repeats what
9 you say.
10 MR. BALL: Adam, I'm allowed
11 make my objections, and he's allowed
12 to hear them.
13 MR. SLATER: All right. Go
14 ahead. I'm trying to get through
15 this. I guess I can't.
16 MR. BALL: No, you're not. I
17 just gave you the form of a question
18 that I would not object to.
19 MR. SLATER: I'll ask a
20 different question, then.
21 I haven't asked the question
22 yet, Dr. Shao.
23 THE INTERPRETER: Okay.
24 MR. SLATER: What did you want

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1 to say?
2 THE INTERPRETER: Go ahead.
3 MR. SLATER: I don't know.
4 Were you asking me something or --
5 THE INTERPRETER: The
6 interpreter needs to re-log on to
7 realtime. Can we just --
8 MR. SLATER: Off the record.
9 Let's go off the record.
10 THE VIDEOGRAPHER: The time
11 right now is 10:33 a.m. We're now off
12 the record.
13 (Whereupon, a recess was
14 taken.)
15 THE VIDEOGRAPHER: The time
16 right now is 10:36 a.m. We're back on
17 the record.
18 BY MR. SLATER:
19 Q. You stated earlier that back in
20 2011, at that time nobody had any knowledge
21 on nitrosamine impurities, including its
22 detection methods.
23 However, here in a 1978 IARC
24 monograph, it specifically says here that the

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1 principal techniques used are high- and
2 low-resolution mass spectrometry.
3 MR. BALL: Objection. That
4 mischaracterizes his earlier
5 testimony.
6 Go ahead and answer.
7 BY MR. SLATER:
8 Q. Correct?
9 Wait. Actually, I'll ask it
10 differently, then.
11 This publication in 1978 says
12 that the principal technique to analyze
13 volatile nitrosamines, which would include
14 NDMA and then DMA, is high- and
15 low-resolution mass spectrometry.
16 Did ZHP know that in 2011?
17 A. I would like to ask you what
18 publication you're referring to that's
19 published in 1978. Is that the document
20 that's presented on the screen?
21 Q. Yes.
22 A. Can you point out which
23 sentence on this paragraph you are referring
24 to?

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1 Q. Why? Can you read English?
2 A. You just mentioned about the
3 high-resolution mass spectrometry. I want to
4 make sure high-resolution mass spectrometry
5 is indeed referred to in this paragraph.
6 Q. But if I show you where it is
7 in the paragraph, if you can't read English,
8 how is that going to help you for me to point
9 out where it is?
10 A. At least I can confirm that it
11 was indeed mentioned in the publication in
12 1978.
13 Q. But you don't read English, so
14 how is it going to help you for me to point
15 out where it says it in this paragraph? Are
16 you going to read it?
17 A. I just want to confirm that
18 what you just said is indeed included in the
19 publication in 1978, rather than your own
20 understanding and judgment.
21 Q. Mr. Dong, I would appreciate it
22 if you would actually answer my question.
23 Do you speak English?
24 Let me -- why are you asking to

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1 know where it is in the paragraph when you've
2 already told us under oath that you can't
3 read this language?
4 A. I did say that I cannot read
5 English. That's a fact. However, I believe
6 I'm entitled to know that statement was
7 indeed included in a publication in 1978. I
8 want to confirm it is a fact.
9 Q. Okay. Then why don't you do
10 this, Mr. Dong.
11 Do you see this paragraph in
12 front of us? Why don't you read what you can
13 of that paragraph. Since you're going to
14 confirm it, confirm it out loud for us,
15 please. You'll see it in the fifth line,
16 sixth line, you'll see it. Fifth line.
17 MR. BALL: Objection.
18 Harassment.
19 MR. SLATER: It's not
20 harassment.
21 MR. BALL: It is.
22 MR. SLATER: The witness said
23 he wants to confirm this by reading it
24 himself, so I'm telling him --

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1 MR. BALL: No, he did not say
2 he wanted to --
3 BY MR. SLATER:
4 Q. It's the fifth line.
5 MR. BALL: He did not say he
6 wanted to read it himself. That
7 mischaracterizes what he said. He
8 said he'd like you to tell him where
9 it is.
10 Tell him where it is, and we
11 can go on.
12 MR. SLATER: Great. It's in
13 the fifth line, it starts.
14 A. Could you repeat your question?
15 Had that not been the discussion, I would
16 have recalled the question.
17 BY MR. SLATER:
18 Q. I have no idea what my question
19 was. You totally distracted me. You
20 defeated me on that one.
21 MR. SLATER: Maureen, if you
22 can find that for me, can you remind
23 me what my question was, please?
24 ///

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1 (Whereupon, the reporter read
2 back the requested question.)
3 A. In 2011, ZHP had no knowledge
4 of the formation of NDMA in valsartan zinc
5 chloride process.
6 When nobody had such knowledge,
7 there was no reason to adopt additional
8 method to test unexpected impurities or the
9 impurities that we were unable to speculate.
10 That is basically beyond our expectation.
11 As for your statement that I
12 successfully distracted you just now, that's
13 not true. I was merely asking you to be more
14 specific and clear for your questions.
15 BY MR. SLATER:
16 Q. So you won't answer my
17 question?
18 A. I believe I've already provided
19 a response to your question.
20 In 2011, during the development
21 of valsartan zinc chloride process, ZHP did
22 not have any specific knowledge of the
23 formation of NDMA in the valsartan zinc
24 chloride process.

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1 When nobody had such specific
2 knowledge, I don't believe we take into
3 consideration any further approaches.
4 MR. SLATER: Okay. Let's take
5 this document down. I give up. Move
6 on to the next thing.
7 Take that down, Cheryll. Let's
8 go to the other document that I
9 started to identify before, the
10 deviation -- perfect.
11 (Whereupon, Exhibit Number
12 ZHP-210 was marked for
13 identification.)
14 BY MR. SLATER:
15 Q. Exhibit 210. Mr. Dong, you've
16 seen this document before, correct?
17 A. I did review a deviation
18 investigation report with the number
19 DCE-18003. However, I cannot be 100 percent
20 sure the document I reviewed was completely
21 consistent with the document shown on the
22 screen.
23 MR. SLATER: Let's go to the
24 next page, Cheryll.

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1 Thank you.
2 Q. Here on the page with Bates
3 number 75798, there's a list of people who
4 reviewed and approved this report. Your name
5 appears, and you signed this report, correct?
6 A. That's correct. As shown on
7 the screen, on the third line my name was
8 listed here. I did review and approve this
9 report.
10 MR. SLATER: Let's go to page 5
11 of 236.
12 Q. Section 3.1.1 is the "NDMA
13 Event Description."
14 Do you see that?
15 A. I see it under 3.1.1. There's
16 a Chinese sentence which says "Valsartan
17 (zinc chloride process) NDMA Event General
18 Description."
19 Q. In the first paragraph it
20 refers to -- rephrase.
21 At the end of the first
22 paragraph, it says, "Please refer to
23 Deviation Investigation No.: DCE-18001 for
24 details."

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1 My question is, have you seen
2 that report in Chinese, meaning in the
3 Chinese language, DCE-18001?
4 A. I did review the deviation
5 investigation report with the number
6 DCE-18001.
7 Q. In the Chinese language?
8 A. I only read the Chinese
9 version. I do not recall whether the
10 document I reviewed was only the Chinese
11 version or the bilingual version in both
12 Chinese and English.
13 Q. The second paragraph says in
14 part, "Due to the fact that NDMA is a
15 recently found unexpected impurity with the
16 nature of probable carcinogen, the incident
17 of the deviation has received great attention
18 from Huahai's top management."
19 Does top management go all the
20 way up to Baohua Chen? Did he give his great
21 attention to this issue?
22 MR. BALL: Adam, can you scroll
23 down, please? I can't read. You have
24 to scroll down. I can't see it.

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1 A. I'm sorry, I don't know who
2 you're referring to by "Baohua Chen."
3 Q. Mr. Chen, the chairman of ZHP.
4 A. Are you referring to the
5 chairman of ZHP Baohua Chen, spelled as
6 B-O-H-U-A, C-H-E-N?
7 Q. Yes.
8 A. Now I understand. I believe
9 there was a misspelling in the English
10 version. That's why I didn't hear very
11 clearly. I'm sorry.
12 I'm sorry. Can you repeat your
13 question?
14 Q. You don't remember my question?
15 A. I'm sorry. We just had some
16 discussion about a person's name. I do not
17 recall the question. I'm sorry.
18 Q. When this paragraph refers to
19 the issue having "received great attention
20 from Huahai's top management," does that
21 include Mr. Chen, the chairman of ZHP?
22 A. I believe after this incident
23 happened, some company leaders reported this
24 incident to Mr. Chen.

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1 Q. Do you know who did that?
2 A. I don't know. Actually, there
3 are quite a few levels between my pay level
4 and Mr. Chen.
5 Q. You said people informed him.
6 Which people?
7 A. I don't know who specifically
8 informed him. However, with regard to the
9 seriousness of this incident, to the best of
10 my understanding, there must be someone who
11 reported this incident to Mr. Chen.
12 Q. This says a little further
13 down, "NDMA reference standard was
14 immediately purchased and the identity of the
15 impurity was confirmed as NDMA by GC-MS
16 method."
17 Do you see that? Yes or no.
18 Do you see that? Yes or no.
19 A. On the screen I do see the
20 sentence referred to by you. It is one of
21 the sentences in the Deviation Investigation
22 Report with the number DCE-18003.
23 MR. SLATER: Maureen, could you
24 read that answer back to me, please?

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1 (Whereupon, the reporter read
2 back the above answer.)
3 BY MR. SLATER:
4 Q. Were you in charge of the --
5 actually, you know what, we'll get to that.
6 We'll get to that.
7 MR. SLATER: Let's go to
8 page 60, please.
9 MR. BALL: Adam, we have about
10 five minutes before the next break.
11 MR. SLATER: So what do you
12 want to do?
13 MR. BALL: It's up to you. I'd
14 like to talk to you. We can go off
15 the record now --
16 MR. SLATER: All right. Let's
17 go off the record.
18 MR. BALL: I just need to
19 clarify something with you.
20 THE VIDEOGRAPHER: The time
21 right now is 11:07 a.m. We're now off
22 the record.
23 (Whereupon, a recess was
24 taken.)

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1 THE VIDEOGRAPHER: The time
2 right now is 11:20 a.m. We're back on
3 the record.
4 BY MR. SLATER:
5 Q. Section 4 -- rephrase.
6 Table 4-2 is titled
7 "Differences in different Valsartan
8 manufacturing process."
9 Do you see that?
10 A. I see it.
11 MR. SLATER: Let's go to the
12 next page, please, page 61.
13 Scroll down, please.
14 More. I want the bottom box.
15 Yes, perfect. Okay.
16 Q. There's a box that says "TEA
17 process (with sodium nitrite quenching)."
18 Do you see that?
19 This was the process used
20 before the zinc chloride process was put into
21 effect, right?
22 A. I'm sorry. Are you referring
23 to the box that says "TEA process (with
24 sodium nitrite quenching)"? Are you

<p style="text-align: right;">Page 433</p> <p>1 referring to this box?</p> <p>2 Q. Yes. That's exactly what I</p> <p>3 just identified for you a question ago.</p> <p>4 A. Yes, I see it.</p> <p>5 Q. Did you study English at</p> <p>6 university?</p> <p>7 A. I did study English at college;</p> <p>8 however, I did poor in English class.</p> <p>9 Q. Did you have to demonstrate</p> <p>10 English proficiency in order to graduate?</p> <p>11 A. I'm sorry to tell you that in</p> <p>12 order to graduate from a college in China,</p> <p>13 you have to pass level 4 English test. For</p> <p>14 that test, I took six or seven times until</p> <p>15 finally I passed that test. I'm sorry.</p> <p>16 Q. Did you read English language</p> <p>17 material when you were studying chemistry?</p> <p>18 A. Are you referring to my time in</p> <p>19 college?</p> <p>20 Q. Yes.</p> <p>21 A. No.</p> <p>22 Q. Let's look at this box now.</p> <p>23 Rephrase.</p> <p>24 We're looking now at the "TEA</p>	<p style="text-align: right;">Page 435</p> <p>1 deviation investigation report shown on the</p> <p>2 screen, I do see such description.</p> <p>3 Q. And based on ZHP's evaluation,</p> <p>4 that actually was occurring, correct? That's</p> <p>5 how NDMA and NDEA were being formed, with the</p> <p>6 TEA process with sodium nitrite quenching,</p> <p>7 right?</p> <p>8 A. I'm sorry, your question is a</p> <p>9 little bit too long, and I didn't quite get</p> <p>10 your question.</p> <p>11 What are you referring to by</p> <p>12 "that actually was occurring"? What's</p> <p>13 "that"?</p> <p>14 Q. Number 3 describes the root</p> <p>15 cause for the NDMA and NDEA impurities in the</p> <p>16 TEA process with sodium nitrite quenching</p> <p>17 valsartan, correct?</p> <p>18 A. With regard to the NDEA and</p> <p>19 NDMA impurities that were generated from the</p> <p>20 TEA process of valsartan, in 2018, after NDMA</p> <p>21 impurity was discovered in valsartan, ZHP</p> <p>22 conducted the process deviation</p> <p>23 investigation, and this was one of the</p> <p>24 findings in the investigation.</p>
<p style="text-align: right;">Page 434</p> <p>1 process (with sodium nitrite quenching)."</p> <p>2 And it first says, number 1, "Triethylamine</p> <p>3 hydrochloride was used as catalyst. Sodium</p> <p>4 nitrite was used for quenching after</p> <p>5 reaction." Correct?</p> <p>6 A. On the right column in the box</p> <p>7 of "TEA process," I do see description in</p> <p>8 Chinese that's basically consistent with your</p> <p>9 quote.</p> <p>10 Q. Number 2 says, "No DMF solvent</p> <p>11 is added in crude step, and no dimethylamine</p> <p>12 will be degraded."</p> <p>13 Do you see that?</p> <p>14 A. Yes. In the line of "TEA</p> <p>15 process" on the third column from left, I do</p> <p>16 see your description in Chinese.</p> <p>17 Q. Number 3 says, "Triethylamine</p> <p>18 hydrochloride may contain diethylamine and</p> <p>19 dimethylamine, react with nitrous acid</p> <p>20 (formed by sodium nitrite and hydrochloric</p> <p>21 acid) during the next quenching reaction, and</p> <p>22 NDMA and NDEA may be formed."</p> <p>23 Do you see that?</p> <p>24 A. Yes, I see it. In the</p>	<p style="text-align: right;">Page 436</p> <p>1 Q. The risk assessment for TEA</p> <p>2 process with sodium nitrite quenching failed</p> <p>3 to disclose this potential risk for this</p> <p>4 contamination as described in number 3,</p> <p>5 correct?</p> <p>6 A. In 2011, the authorities, the</p> <p>7 industry, and ZHP did not have any knowledge</p> <p>8 regarding the formation of nitrosamines in</p> <p>9 the valsartan TEA process.</p> <p>10 Q. Answer my question, please.</p> <p>11 A. I believe I've already offered</p> <p>12 my response to your question.</p> <p>13 Q. ZHP failed to identify the risk</p> <p>14 of these impurities forming as part of its</p> <p>15 risk assessment for the TEA process with</p> <p>16 sodium nitrite quenching, correct?</p> <p>17 A. In 2011, the authorities, the</p> <p>18 industry, or ZHP did not have any knowledge</p> <p>19 of the formation of nitrosamines in the</p> <p>20 valsartan triethylamine process.</p> <p>21 MR. BALL: Adam, I think he's</p> <p>22 trying to answer your question. Would</p> <p>23 you like me to rephrase it in a way he</p> <p>24 might be able to answer it more</p>

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1 easily?

2 MR. SLATER: If it's going to

3 help.

4 MR. BALL: I think it might.

5 In 2011, did ZHP identify that

6 NDMA or NDEA could be formed as part

7 of the TEA process when it conducted

8 its risk analysis?

9 And that's a yes -- if he can

10 answer that yes or no, we would all

11 appreciate it.

12 A. I would like to ask you whether

13 my attorney correctly characterized your

14 question or what you wanted to ask.

15 BY MR. SLATER:

16 Q. Yes, please answer it with a

17 yes or no.

18 THE INTERPRETER: The

19 interpreter is asked to repeat the

20 rendition of the question provided by

21 the witness attorney.

22 A. In 2011, when ZHP conducted the

23 risk assessment for the TEA process, ZHP did

24 not identify tri- -- did not identify

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1 nitrosamines as potential impurities. That

2 was based on the knowledge of the

3 authorities, the industry, and ZHP at that

4 time.

5 Q. ZHP certainly knew by 2011 --

6 rephrase.

7 ZHP knew in 2011 that the

8 reaction of dimethylamine and a nitrosating

9 agent such as nitrous acid could form NDMA,

10 correct?

11 A. In 2011, ZHP did not have any

12 knowledge of the formation of nitrosamine in

13 the valsartan zinc chloride process or the

14 TEA process.

15 MR. SLATER: Let's go to the

16 next page, the box at the top half of

17 the page, please.

18 Excellent.

19 Q. This box now addresses the zinc

20 chloride process.

21 Do you see that?

22 A. Yes. I see that on the screen

23 there's a box for the zinc chloride process.

24 Q. And on the right-hand side this

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1 says, starting with number 2, "Zinc chloride

2 is used as catalyst for the crude step of

3 valsartan (zinc chloride process)."

4 Do you see that?

5 A. Yes, I see that. What you just

6 described is one of the sentences in the box

7 of the zinc chloride process on the third

8 column.

9 Q. Number 3 says, "DMF solvent was

10 added in the crude step. DMF was degraded

11 into dimethylamine, react with nitrous acid

12 (formed by sodium nitrite and hydrochloric

13 acid) during the next quenching reaction, and

14 NDMA may be formed."

15 Do you see that?

16 A. Yes, I see that as part of the

17 content under number 3 in the line of "Zinc

18 chloride process" under the column of -- the

19 first column from the right.

20 Q. That is the root cause for the

21 NDMA contamination of the zinc chloride

22 process valsartan, correct?

23 A. What you just said, "NDMA

24 contamination," I need to point out that

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1 NDMA, rather, is an impurity formed in the

2 valsartan zinc chloride process. It is not a

3 contaminant. We did not have such knowledge

4 until June 2018.

5 As for the definitions for the

6 impurities and the contaminants,

7 respectively, you may find accurate

8 descriptions in ICH Q3A.

9 Q. Number 4 says, "Without

10 introducing triethylamine, diethylamine would

11 not be introduced and no NDEA would be

12 formed."

13 Do you see that?

14 A. I see that under number 4 in

15 the box of "Zinc chloride process" under the

16 first column from right.

17 Q. The reason that is referred to

18 there is because the triethylamine with the

19 sodium nitrite quenching process was

20 combining with nitrous acid, NDEA, in that

21 process, correct?

22 A. The interpreter's translation

23 was very clear; however, I do not understand

24 your question. Could you be more specific or

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1 clear?
2 Q. Why is that sentence --
3 rephrase.
4 What is the purpose of that
5 sentence, number 4? Why is that stated?
6 A. In this box under number 4, I
7 do see what you just talked about.
8 As for the reason why this
9 sentence is here, I need to have a quick
10 review of the context in order to provide you
11 with an answer.
12 MR. SLATER: Let's go off the
13 clock.
14 A. Can you scroll up a little bit?
15 I need to read the content above this box.
16 Just scroll up until I see the first page.
17 MR. BALL: I think he's talking
18 the other direction. The other
19 direction.
20 There we go.
21 MR. SLATER: I'm glad you're
22 doing this, Cheryll, and not me.
23 A. Keep going. Keep going until I
24 see the top of this table.

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1 MR. BALL: There we go.
2 A. Just keep going.
3 MR. BALL: I think she may have
4 gone too far. He said he wanted to
5 see the top of the table.
6 A. Keep going.
7 MR. SLATER: The top of the
8 table is on page 60.
9 MR. BALL: Okay. Thank you.
10 Thank you. Adam.
11 A. I need to see. I need to see
12 what's above this Table 4-2. Keep going.
13 Keep going. Keep going.
14 That's it.
15 I finished reviewing.
16 MR. BALL: We can go back on
17 the clock, please.
18 MR. SLATER: Wait, let's get to
19 the spot first. Hang on.
20 MR. BALL: Okay.
21 MR. SLATER: Almost there.
22 Bingo.
23 BY MR. SLATER:
24 Q. Okay. Please answer the

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1 question.
2 Why is sentence number 4 there?
3 What is that communicating to us?
4 A. After reviewing part of this
5 document, I found out that this table is
6 actually describing the differences between
7 different valsartan processes.
8 In the table analysis, the
9 formation of nitrosamines was conducted for
10 different valsartan processes. That was
11 based on the knowledge that ZHP did not
12 obtain until June 2018.
13 More specifically, regarding
14 number 4, in my personal opinion, maybe that
15 is because comments on the specific impurity
16 was made in the previous process analysis;
17 therefore, comments on NDEA is also included
18 here. That's my personal opinion.
19 Q. When you say this was not known
20 in 2011, are you saying it was not known that
21 amines, A-M-I-N-E-S, had been demonstrated to
22 react with nitrous acid to produce
23 nitrosamines?
24 MR. BALL: Objection. Vague.

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1 A. Are you referring to 2011? I
2 just want to confirm time frame.
3 BY MR. SLATER:
4 Q. Yes.
5 A. In 2011, ZHP did not have any
6 knowledge of the formation of nitrosamine in
7 the valsartan manufacturing processes,
8 including valsartan zinc chloride process and
9 valsartan TEA quenching process. This
10 applies to the industry and the authority at
11 that time, too.
12 Q. I'll try it again.
13 Are you saying that ZHP did not
14 know in 2011 that amines, A-M-I-N-E-S, had
15 been demonstrated to react with nitrous acid
16 to produce N-nitrosamines?
17 A. I've already provided an answer
18 to your question. If you want to try the
19 same question again, could you please
20 clarify, when you say "amines," are you
21 referring to the primary amines, secondary
22 amines, or tertiary amines? Are you
23 referring to amines with certain molecular
24 weights?

<p style="text-align: right;">Page 445</p> <p>1 Q. Any amines, you tell me, which 2 ZHP knew about that could react with nitrous 3 acid to produce nitrosamines in 2011. 4 A. I just asked to you clarify 5 certain vague terms in your question in order 6 for me to provide you with a more accurate 7 response. 8 Based on the current knowledge 9 regarding the formation of nitrosamines, not 10 all forms of amines would form nitrosamine. 11 That's the knowledge we have as of now. 12 Maybe in 100 years or 13 500 years, the investment of the science and 14 technology will provide us with new 15 discoveries. Maybe. 16 MR. SLATER: Cheryll, I don't 17 want to lose this page, but I'd like 18 to bring up an article that I think 19 you have now, and I think we're up to 20 Exhibit 211. 21 Perfect. 22 (Whereupon, Exhibit Number 23 ZHP-211 was marked for 24 identification.)</p>	<p style="text-align: right;">Page 447</p> <p>1 BY MR. SLATER: 2 Q. Was ZHP -- rephrase. 3 In ZHP's thorough scientific 4 analysis during its risk assessment for the 5 TEA process with sodium nitrite quenching and 6 for the zinc chloride process in 2011, did 7 the risk assessment team read this article? 8 A. As to whether ZHP's valsartan 9 risk assessment team read this article in 10 2011, as you asked, I am unable to provide an 11 accurate response because this is the first 12 time I ever see this document. 13 Based on the information I 14 collected as well as the documents I reviewed 15 as a corporate witness, in 2011 ZHP had no 16 knowledge of the formation of nitrosamines in 17 valsartan manufacturing process, which 18 include zinc chloride process as well as the 19 TEA process. 20 Q. Is diethylamine a secondary or 21 tertiary amine? 22 A. From the chemistry's 23 perspective, the diethylamine is a secondary 24 amine.</p>
<p style="text-align: right;">Page 446</p> <p>1 BY MR. SLATER: 2 Q. On the screen is Exhibit 211, 3 which is a journal article published in the 4 "Journal of Physical Chemistry" in 2010, 5 titled "Theoretical Investigation of 6 N-Nitrosodimethylamine Formation from 7 Nitrosation of Triethylamine." 8 And the authors' names are Zhi 9 Sun, Yong Dong Liu, and Ru Gang Zhong, and it 10 says they're from the College of Life Science 11 & Bioengineering, Beijing University of 12 Technology in Beijing, and that this was 13 received by this journal June 16, 2009, and 14 then it was received again in November 2009, 15 and it was on the web published December 16, 16 2009. 17 MR. SLATER: And that last 18 thing I said about the publication 19 date is at the bottom, so, Cheryll, in 20 fairness, please scroll to the bottom 21 so Mr. Ball can see it. And I'm sure 22 it's in our chat, too. 23 MR. BALL: Thank you. 24 MR. SLATER: No problem.</p>	<p style="text-align: right;">Page 448</p> <p>1 Q. Is dimethylamine also a 2 secondary amine? 3 A. That's correct. The 4 dimethylamine is also a secondary amine. 5 Q. This says in the second 6 paragraph, "Because dialkylnItrosamines are 7 of great interest in carcinogenesis, much 8 attention has been focused on their formation 9 mechanism, especially from secondary amines." 10 I'm going to stop there. 11 They say "much attention has 12 been focused on their formation...from 13 secondary amines." Was any attention focused 14 on their formation mechanism from secondary 15 amines by ZHP in 2011? 16 A. What ZHP was focusing on in 17 2011 was to produce products with quality 18 specifications that would be in compliance 19 with the ICH requirement, and ZHP's knowledge 20 at that time, including the valsartan 21 products. 22 As for the research of the 23 formation mechanism of nitrosamines, I 24 believe it was the interest of independent</p>

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1 academic people.
 2 Also, based on what you have
 3 just said and what has been translated to me
 4 in your question, you mentioned something
 5 like a secondary amine.
 6 In ZHP's valsartan
 7 manufacturing processes, in particular in the
 8 valsartan zinc chloride process, DMF was used
 9 as a solvent. From the chemical point of
 10 view, DMF is an amide, spelled as A-M-I-D-E.
 11 It's not a secondary amine.
 12 In the valsartan TEA
 13 hydrochloride process, triethylamine is a
 14 tertiary amine, not a secondary amine.
 15 That's all I have to say.
 16 MR. SLATER: Maureen, can you
 17 just read back the last sentence of
 18 what was just translated as the
 19 answer, please?
 20 (Whereupon, the reporter read
 21 back the above answer.)
 22 Q. This article states in the
 23 second paragraph in part, "Consequently, NDMA
 24 is generally believed to be formed from the

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1 reactions of dimethylamine (DMA) and
 2 nitrosating agents, such as N2O3, N2O4, and
 3 ONCl. In addition to secondary amines,
 4 however, a wide variety of tertiary amines
 5 have also been demonstrated to react with
 6 nitrous acid to produce N-nitrosamines in
 7 aqueous solution."
 8 What I just read to you from
 9 this article from 2010, that information was
 10 easily available to ZHP in 2011, correct?
 11 MR. BALL: Objection. Asks for
 12 opinion.
 13 A. I don't agree with -- I don't
 14 agree with your statement that in 2011 ZHP
 15 can easily find that information. That
 16 involves resources as well as methods for
 17 searching for such information. It's nothing
 18 simple.
 19 As for the sentence you just
 20 quoted, from the chemistry point of view, for
 21 dimethylamine, or DMA, as well as chemicals
 22 such as N2O3, N2O4, ONCl, ZHP did not use any
 23 of those chemicals directly in our
 24 manufacturing processes.

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1 What I mean is that these
 2 chemicals are not the raw materials used in
 3 the process.
 4 MR. BALL: Adam, it's probably
 5 about time for a break.
 6 MR. SLATER: Okay. Let's go
 7 off.
 8 THE VIDEOGRAPHER: The time
 9 right now is 12:22 p.m. We're now off
 10 the record.
 11 (Whereupon, a recess was
 12 taken.)
 13 THE VIDEOGRAPHER: The time
 14 right now is 12:35 p.m. We're back on
 15 the record.
 16 BY MR. SLATER:
 17 Q. If ZHP had figured out that
 18 diethylamine and/or dimethylamine was a
 19 potential degradation product of either of
 20 these manufacturing processes for valsartan,
 21 they would have had to change the processes
 22 to avoid the nitrosating reactions, correct,
 23 back in 2011?
 24 A. This is a hypothetical

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1 question. I don't answer any hypothetical
 2 question.
 3 However, with that, in 2011,
 4 ZHP conducted corresponding work based on our
 5 knowledge at that time, as well as the
 6 requirements of ICH.
 7 Q. Well, ICH required ZHP to do a
 8 careful scientific analysis in performing its
 9 risk assessment for impurities, correct?
 10 A. In 2011, based on the
 11 requirements of ICH at that time as well as
 12 our knowledge and understanding of valsartan
 13 zinc chloride process, ZHP conducted
 14 corresponding work using scientific methods.
 15 Q. Actually, ZHP did an
 16 insufficient level of research into the
 17 process and failed to figure out the risks
 18 for impurities that it was creating with its
 19 valsartan manufacturing processes in 2011,
 20 correct?
 21 MR. BALL: Objection. Calls
 22 for opinion and expert testimony.
 23 A. In 2011, ZHP conducted
 24 corresponding work using scientific methods

<p style="text-align: right;">Page 453</p> <p>1 based on our knowledge of valsartan zinc 2 chloride process at that time. 3 Meanwhile, the related work was 4 submitted to EDQM and FDA. During this 5 period of time, there were experts who 6 reviewed and approved such work. 7 Q. Which experts reviewed and 8 approved this work? Give me their names, 9 please. 10 A. I'm sorry, I don't know. That 11 is because after we submitted our work to the 12 authorities, we don't know who the 13 authorities hired to conduct the review and 14 approval. 15 Q. You don't know if anybody at 16 the authorities even read what was submitted 17 with regard to the sodium nitrite quenching 18 and zinc chloride processes. You don't even 19 know if anybody there even read what you 20 submitted, correct? 21 A. To the best of my knowledge, 22 after we submitted documents to EDQM, the 23 authority did provide a response. 24 I also know that related</p>	<p style="text-align: right;">Page 455</p> <p>1 already provided responses. 2 In my personal opinion, I 3 personally believe EDQM or FDA as authorities 4 did conduct review and assessment to the 5 valsartan zinc chloride process change. 6 As for the names of the 7 reviewers, I believe that is beyond the scope 8 of 30(b)(6) topics, and that's beyond the 9 scope of information I need to collect. 10 Q. Let's go back to my original 11 question before we went off on this tangent. 12 In evaluating the potential 13 impurities that would potentially form during 14 these processes, the sodium nitrite quenching 15 and the zinc chloride process, there was an 16 insufficient extent and depth of process 17 research, which resulted in the risk 18 assessment failing to identify the risks of 19 nitrosamines, correct? 20 MR. BALL: Objection. Calls 21 for opinion and expert testimony. 22 A. I don't agree with your 23 statement. When we talked about the extent 24 and the depth of the process research, we</p>
<p style="text-align: right;">Page 454</p> <p>1 documents pertaining to valsartan zinc 2 chloride process were also submitted as 3 attachments. 4 Q. It's a simple question. You 5 don't know if anybody actually read anything 6 about the process change details at any 7 authority that your company submitted 8 anything to about the changes, correct? 9 MR. BALL: Objection. Outside 10 the scope of the 30(b)(6) topics. 11 These are regulatory. 12 MR. SLATER: I'm following up 13 on his answer. 14 MR. BALL: That's fine, Adam, 15 I'm not telling him not to answer. 16 MR. SLATER: I understand. I'm 17 just stating for the record why I 18 think it's appropriate to follow up on 19 his response. 20 MR. BALL: Okay. 21 A. In 2011, ZHP already submitted 22 documents regarding valsartan zinc chloride 23 process change to the authorities for review 24 and assessment, and those authorities have</p>	<p style="text-align: right;">Page 456</p> <p>1 need to do that with the background in our 2 mind. Without the background, it is 3 inappropriate to talk about the extent and 4 the steps of the process research. 5 Q. During the risk assessment 6 process, there was insufficient study and 7 understanding of potential genotoxic 8 impurities on the part of the -- on the part 9 of ZHP in evaluating both the sodium nitrite 10 quenching process and the zinc chloride 11 process, which resulted in failing to 12 identify the risk of nitrosamine impurities, 13 correct? 14 MR. BALL: Objection. 15 Compound, calls for opinion, and calls 16 for expert testimony. 17 A. I would like you to be more 18 specific in your question, or ask the 19 questions one by one; therefore, I can 20 provide you with a more accurate response. 21 It's getting late. I'm a little bit tired, 22 I'm sorry. 23 BY MR. SLATER: 24 Q. But it's the morning for you.</p>

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1 We're the ones in the middle of the night.
 2 Okay. It's okay. I'm kidding.
 3 It's okay.
 4 There was insufficient study
 5 and understanding of potential genotoxic
 6 impurities in the risk assessment process for
 7 both the sodium nitrite quenching and zinc
 8 chloride processes in 2011, correct?
 9 MR. BALL: Objection.
 10 Compound, calls for opinion, calls for
 11 expert testimony.
 12 A. The question you just asked is
 13 still a little bit too long, and you can
 14 still ask those questions one by one.
 15 However, for the pending question, I will try
 16 to answer part of your question.
 17 In 2011, ZHP conducted
 18 corresponding work using scientific methods
 19 based on the ICH requirements then, as well
 20 as our knowledge and understanding at that
 21 time. Afterwards the results from that work
 22 were submitted to the authorities.
 23 After the work results were
 24 submitted to the authorities, authorities

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1 such as EDQM provided their recognition and
 2 approval by the corresponding experts of
 3 theirs and provided the approval. The
 4 corresponding approval documents were
 5 included in the valsartan zinc chloride
 6 process change documents in 2011.
 7 Q. I'll try it one last time.
 8 I'm not asking about what
 9 anyone else did, so I would appreciate it if
 10 you would not tell me about regulatory
 11 authorities or people outside ZHP, because
 12 I'm not asking about any of them.
 13 I'm only asking about ZHP and
 14 what it did in its risk assessment.
 15 MR. SLATER: Please translate
 16 that for Mr. Dong so he'll understand
 17 that and understand what I'm asking,
 18 and then I'll ask the question.
 19 Q. Here's my question now, having
 20 given you that background.
 21 In ZHP's risk assessment, ZHP
 22 insufficiently studied and insufficiently
 23 understood the potential genotoxic impurities
 24 as part of its risk assessment, and thus

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1 didn't identify the risk of forming
 2 nitrosamines in the sodium nitrite quenching
 3 and zinc process -- zinc chloride process,
 4 correct?
 5 MR. BALL: Objection. Calls
 6 for opinion, calls for expert
 7 testimony. May be compound; I'm not
 8 entirely sure at this point listening
 9 to it.
 10 A. I don't agree with your
 11 statement. For each and every of your
 12 question, I already provided corresponding
 13 response.
 14 With regard to the external
 15 authorities in your question, for example the
 16 EDQM review and assessment, that is part of
 17 the ZHP's process change. For the process
 18 change application, that is the action that
 19 the regulatory affairs department had to take
 20 and followed up.
 21 Had EDQM not provided the
 22 corresponding approvals certificate, ZHP's
 23 valsartan would have never been sold in the
 24 European market, and ZHP's valsartan zinc

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1 chloride process change would have never been
 2 closed.
 3 I'm just using EDQM as an
 4 example.
 5 MR. SLATER: Cheryll, let's go
 6 to Exhibit 212, please, the next
 7 exhibit.
 8 (Whereupon, Exhibit Number
 9 ZHP-212 was marked for
 10 identification.)
 11 A. I'm sorry, I haven't finished
 12 yet. Should I --
 13 MR. SLATER: Take it down,
 14 then. Let's wait.
 15 BY MR. SLATER:
 16 Q. You hadn't finished. Okay.
 17 A. Thank you very much for letting
 18 me finish my testimony.
 19 In 2011, ZHP conducted
 20 corresponding work using scientific methods
 21 based on the requirements of ICH at that
 22 time, as well as the corresponding knowledge
 23 that ZHP had at that time.
 24 The results of our work were

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1 submitted to the regulatory authorities, such
2 as EDQM, and EDQM as a regulatory authority
3 did provide ZHP with the approval
4 certificate.
5 That's all I have to say.
6 MR. SLATER: Okay. Let's go to
7 the next exhibit now, please, Cheryll,
8 Exhibit 212. And this is ZHP-662283.
9 Scroll back to the top, please.
10 Thanks.
11 Q. And you can see this is an
12 investigation report, and it's regarding the
13 June 6, 2018 date of incident.
14 And there's a list of people
15 that are expected to review and sign, and
16 you're one of the people listed, correct?
17 A. I have two questions for the
18 pending question.
19 First of all, you mentioned
20 that the date for this investigation report
21 is sometime in 2016. I cannot see the date
22 2016 on this report.
23 Secondly, this report, to the
24 best of my recollection, is part of the

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1 investigation, and it's only a draft. I
2 wonder whether a draft can be used as an
3 exhibit.
4 MR. BALL: Adam, would you like
5 me to answer that second question?
6 MR. SLATER: Sure.
7 MR. BALL: Yes.
8 A. Okay. Thank you.
9 BY MR. SLATER:
10 Q. If Dr. Shao said 2016 -- either
11 I said it by accident or -- I don't know, but
12 I'll -- the date of incident is June 6, 2018,
13 to answer your question. That's what I was
14 referring to.
15 Do you see that?
16 A. Thank you. The information is
17 very clear.
18 Q. I'll reask the question, and
19 we'll hopefully get off to a good start here.
20 We're now looking at
21 Exhibit 212, which is a draft of an
22 Investigation Report titled "Investigation
23 regarding an unknown impurity," and then in
24 parenthesis "(Genotoxic Impurity)" for date

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1 of incident June 6, 2018.
2 Do you see that in front of
3 you?
4 A. I see it. On the screen I see
5 the corresponding Chinese description,
6 "Investigation regarding an unknown impurity
7 (Genotoxic Impurity)."
8 MR. SLATER: Please scroll
9 down, Cheryll, to the bottom of this
10 front page.
11 Q. Okay. This says at the
12 bottom -- there's someone named Yuelin Hu,
13 assistant director in the quality assurance
14 department. That's the person who is listed
15 as the custodian of this document.
16 Who is that person?
17 A. I have to make a clarification
18 here.
19 What I see here, the name
20 listed in this table at the bottom is Yuelin
21 Hu. I just want to make sure we're talking
22 about the same person.
23 Q. Yes.
24 A. Yuelin Hu is a colleague of

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1 mine in the QA department. His title is
2 assistant director. He is responsible for
3 reviewing and approving this report. He's
4 not responsible for the custody of this
5 report.
6 MR. SLATER: Let's go, Cheryll,
7 in this document to the page that's
8 Bates-numbered 308, please.
9 Go up a little more.
10 Okay. Perfect. That's good.
11 Q. Looking at paragraph 5.2 with
12 the title "Control strategy" -- do you see
13 that heading right there?
14 A. Can you zoom in a little bit?
15 The font is too small. I cannot see it very
16 clearly.
17 Q. The heading 5.2 says "Control
18 strategy," correct?
19 A. That is correct.
20 Q. And looking now at what it says
21 in this paragraph, it says, "Due to
22 insufficient extent and depth of process
23 research at the early stage, as well as
24 insufficient study and understanding of

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1 potential genotoxic impurities, only side
 2 reaction product and degradation products
 3 were studied, and was unaware of the further
 4 reaction between degradation products and raw
 5 material."
 6 Do you see what I just read?
 7 A. I see that. It's one of the
 8 sentences in the paragraph under Section 5.2
 9 on the screen.
 10 THE INTERPRETER: The
 11 interpreter would like to call it a
 12 night.
 13 MR. BALL: Adam, we have --
 14 yeah, we have like five minutes left.
 15 MR. SLATER: If -- we can go
 16 off the record.
 17 THE VIDEOGRAPHER: The time
 18 right now is 1:18 p.m. We're now off
 19 the record.
 20 (Whereupon, the deposition was
 21 adjourned.)
 22
 23
 24

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1
 2 CERTIFICATE
 3 I, MAUREEN O'CONNOR
 4 POLLARD, Registered Diplomat
 5 Reporter, Realtime Systems
 6 Administrator, and Certified Shorthand
 7 Reporter, do hereby certify that prior
 8 to the commencement of the
 9 examination, PENG DONG, was remotely
 10 duly identified and sworn by me to
 11 testify to the truth, the whole truth,
 12 and nothing but the truth.
 13 I DO FURTHER CERTIFY that
 14 the foregoing is a verbatim transcript
 15 of the testimony as taken
 16 stenographically by and before me at
 17 the time, place, and on the date
 18 hereinbefore set forth, to the best of
 19 my ability.
 20 I DO FURTHER CERTIFY that
 21 I am neither a relative nor employee
 22 nor attorney nor counsel of any of the
 23 parties to this action, and that I am
 24 neither a relative nor employee of
 such attorney or counsel, and that I
 am not financially interested in the
 action.

 MAUREEN O'CONNOR POLLARD
 NCRA Registered Diplomat Reporter
 Realtime Systems Administrator
 Certified Shorthand Reporter
 Notary Public
 Dated: April 2, 2021

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1 INSTRUCTIONS TO WITNESS
 2
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it. It will be
 10 attached to your deposition.
 11 It is imperative that you return
 12 the original errata sheet to the deposing
 13 attorney within thirty (30) days of receipt
 14 of the deposition transcript by you. If you
 15 fail to do so, the deposition transcript may
 16 be deemed to be accurate and may be used in
 17 court.
 18
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 2 E R R A T A
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 4 PAGE LINE CHANGE
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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
Hereby certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

PENG DONG DATE

Subscribed and sworn
To before me this
_____ day of _____, 20____.

My commission expires: _____

Notary Public

LAWYER'S NOTES

PAGE LINE

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